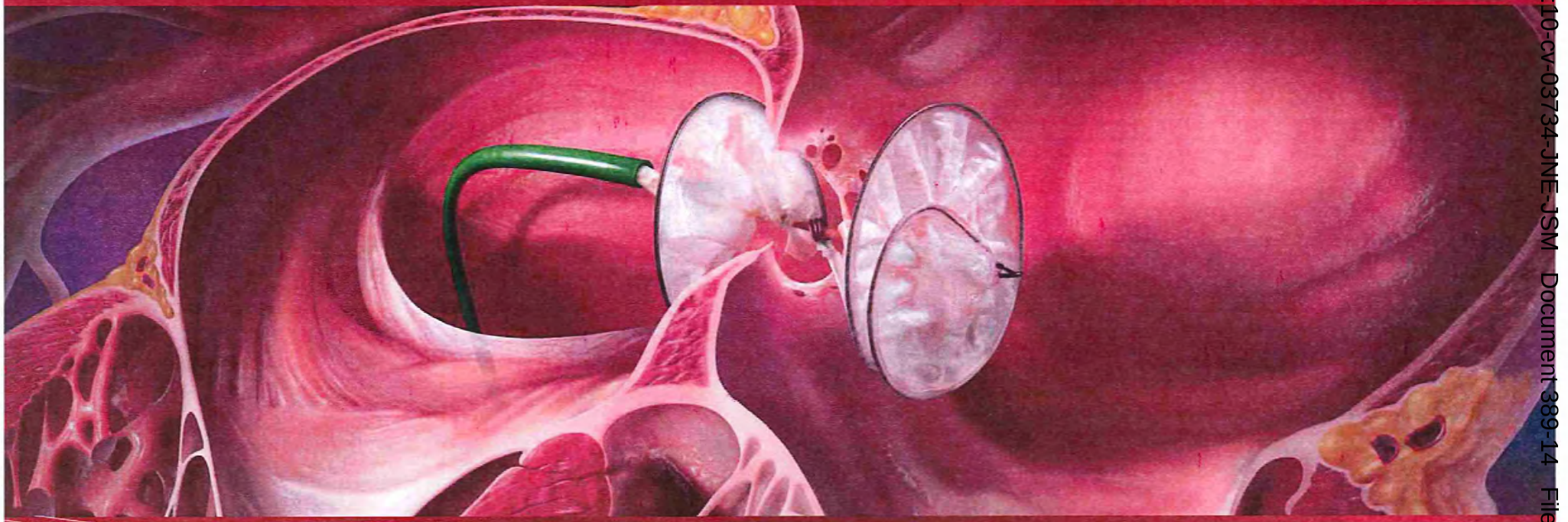
Exhibit 6

TRAINING MANUAL



PERFORMANCE by design

GORE

HELEX

SEPTAL OCCLUDER

AGA_GORE0442691

Contents

Special thanks to the following cardiologists for input and guidance in the use of the GORE HELEX Septal Occluder:

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Neil Wilson, MD
Evan Zahn, MD
Thomas Zellers, MD

GORE HELEX SEPTAL OCCLUDER

Consult Instructions for Use

History

Since the early 1980s, experience in the transcatheter closure of atrial septal defects has demonstrated the importance of several features for an ideal closure device. Our research showed cardiologists felt that an Occluder should be quick and easy to deploy, visible under echocardiography, forgiving of errors, and readily removable even when partially or fully deployed. From a patient safety perspective, the device should present minimal risk of thrombosis, trauma or late erosion or penetration of any cardiovascular structures.

The GORE HELEX Septal Occluder is one of a family of Gore interventional products recently designed for transcatheter implantation. These endovascular and cardiac products represent a new era in treatment of vascular and cardiac diseases.

W. L. Gore & Associates (Gore) has been manufacturing high value expanded polytetrafluoroethylene (ePTFE) products for the cardiac, vascular, general, orthopedic and oral surgical markets for more than 30 years, with more than 25 million clinical implants. Gore ePTFE has been used in cardiovascular surgery in atrial septal defect (ASD) closure since 1982. In 1996, Gore began development of an interventional septal defect closure device. As development progressed, the company sought the advice and consultation of leading pediatric interventional cardiologists and cardiac surgeons.

"The GORE HELEX Septal Occluder (W. L. Gore & Associates, Flagstaff, Arizona) is a new device with many desirable characteristics. These include direct placement of the delivery catheter across the septal defect without the need for a long sheath: rounded, flexible and atraumatic shape; easy deployment while maintaining the ability to withdraw the device back into the delivery system at any time prior to release; safety cord to allow for removal of the device even after release from the formed elements of the delivery system; and highly biocompatible expanded polytetrafluoroethylene (ePTFE) covering. The design of the device has been thoroughly tested by computer modeling in vitro testing and in vivo evaluations in an animal model of atrial septal defect (ASD). Early human experience in Europe for ASD and patent foramen ovale (PFO) indications has been encouraging..."[1]

1995-96	Prototype development
1997-98	Pre-clinical testing
1999	CE marked in June
2000	US Feasibility Study initiated in April
2001	US Pivotal Study initiated in March
2003	US Continued Access Study with hydrophilic-coated ePTFE initiated in May
2006	FDA Approval of GORE HELEX Septal Occluder 1.1
2007	FDA Approval of GORE HELEX Septal Occluder with 1.5 Delivery System
2010	FDA Approval of GORE HELEX Septal Occluder with the 2.0 Delivery System

Latson LA, Zahn EM, Wilson N. Helex Septal Occluder for closure of atrial septal defects. Current Interventional Cardiology Reports 2000;2(3):268-273.

Consult Instructions for Use

GORE HELEX SEPTAL OCCLUDER

Features

SIMPLICITY OF DESIGN

- Compliant circular shape.
- Flat profile.
- ePTFE occlusion membrane.
  — Hydrophilic coating to enhance ultrasound visibility.
- Circumferential Nitinol support frame, completely contained within ePTFE.
  — Low metal mass.
  — Minimal nickel leaching.

SIMPLICITY OF OPERATION

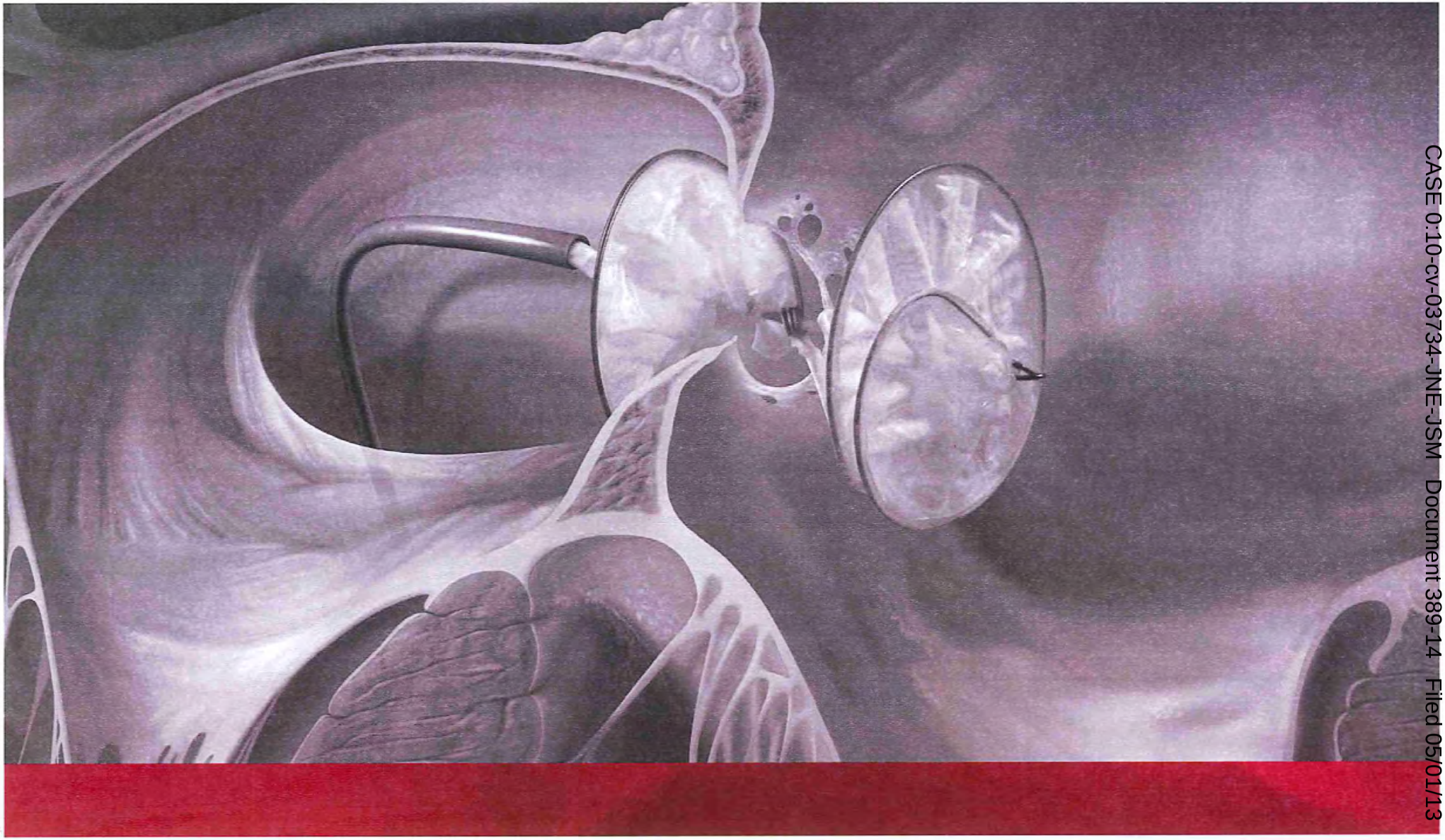
- Utilizes standard interventional techniques.
- Universal sheathless delivery system (10 Fr).
  — Pre-formed catheter for direct access to the septal defect.
  — Optional guidewire port.
- Easily repositioned.
- Easily retrieved using delivery system.
- Allows accurate assessment of septal occlusion prior to final release from the delivery system.

ePTFE MEMBRANE MATERIAL

- ePTFE material performance is proven in more than 25 million clinical implants.
- Reduced thrombogenicity.
- Controlled tissue response: microporous surface allows thin and firm tissue attachment without exuberant tissue formation.
- Biocompatible ePTFE material supports the formation of a functional intimal cell lining.

Consult Instructions for Use

GORE HELEX SEPTAL OCCLUDER

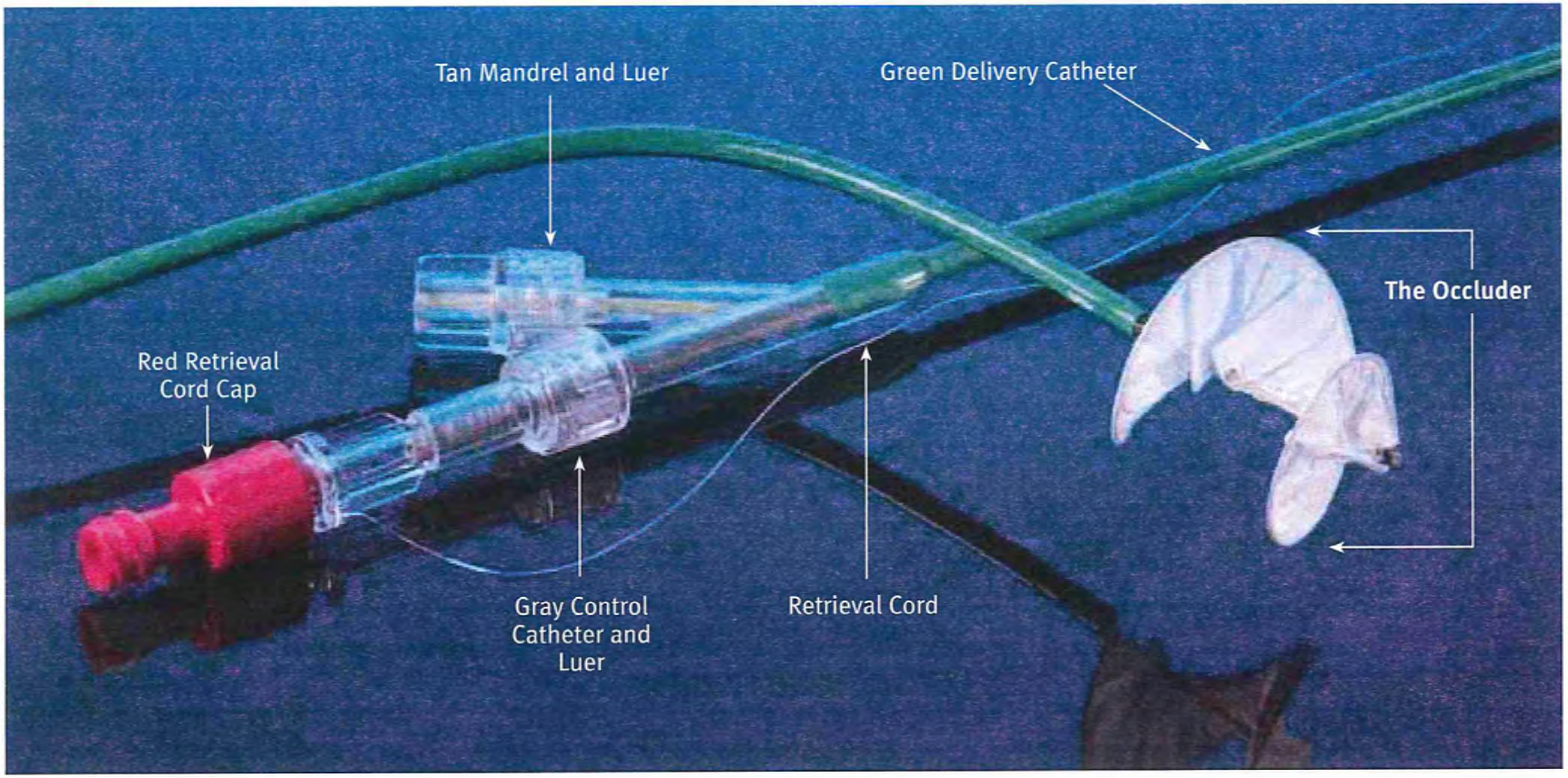


PRODUCT

GORE HELEX SEPTAL OCCLUDER

AGA_GORE0442695
C-1

Product Components



Consult Instructions for Use

GORE HELEX SEPTAL OCCLUDER

AGA_GORE0442696
C-2

Occluder

The GORE HELEX Septal Occluder consists of compliant discs of ePTFE, circumferentially supported by Nitinol wire. The entire Occluder frame is constructed from a single Nitinol wire (Fig. C-2). Microporous ePTFE material, bonded to the Nitinol frame, is designed to encourage early tissue attachment, improving the security of the Occluder and reducing the potential for residual leakage. Perforations along the central edge of the ePTFE membrane are provided to align the material on the delivery system and are captured by the locking loop (Fig. C-1).

The GORE HELEX Septal Occluder is supplied in diameters of 15, 20, 25, 30, and 35 mm.

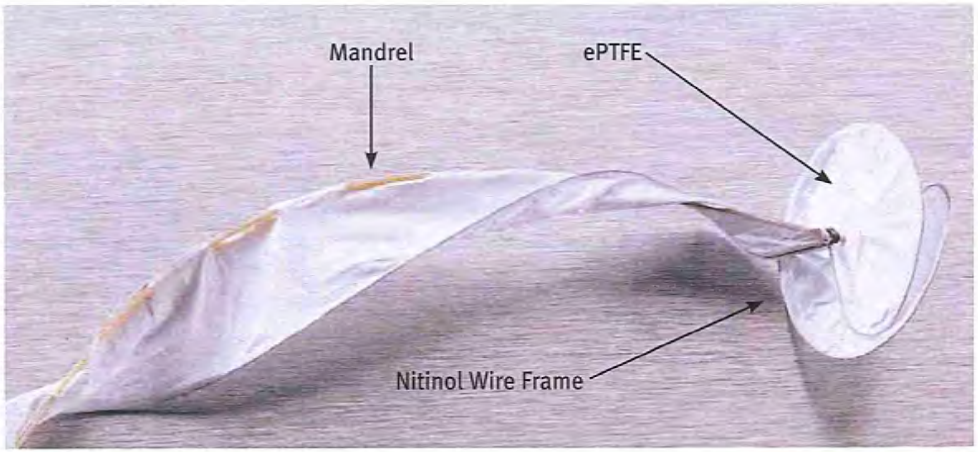


Figure C-1

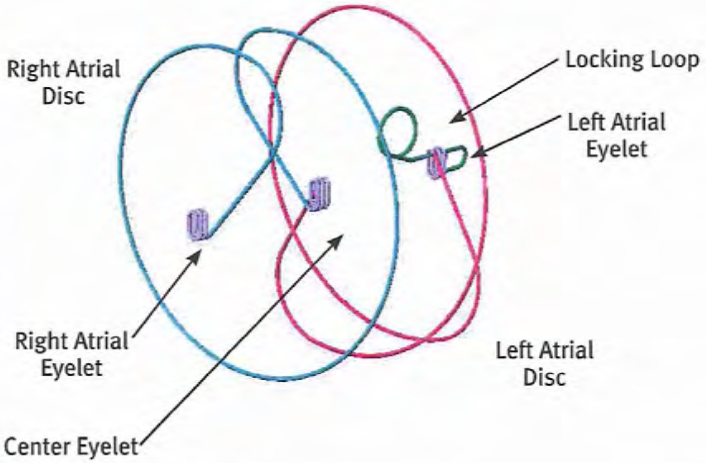


Figure C-2 – Nitinol Wire Frame Design

Consult Instructions for Use

GORE HELEX SEPTAL OCCLUDER

Occluder

HYDROPHILIC TREATMENT

Standard microporous ePTFE membrane is hydrophobic and can interfere with echocardiographic evaluation. Since ultrasound assessment is essential to evaluation of appropriate Occluder placement, the membrane has been treated to render it hydrophilic and enhance ultrasound visibility.

When placed in heparinized saline during the loading procedure described in the deployment section of this manual, the membrane will absorb the liquid and become transparent.

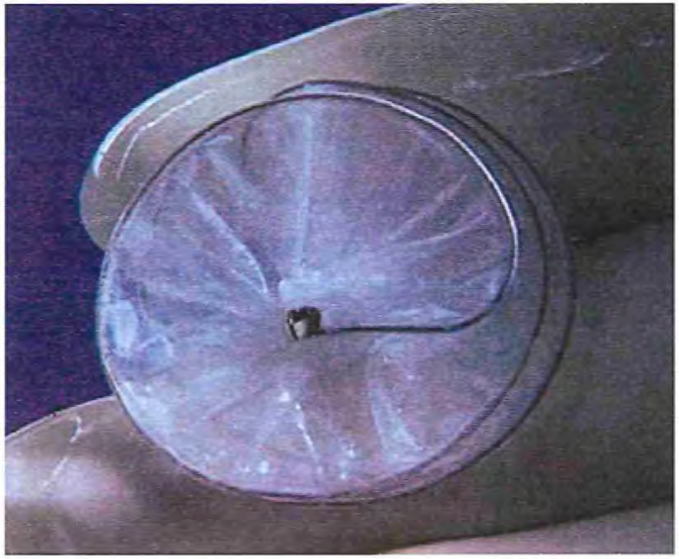


Figure C-3 – Hydrophilic-treated ePTFE membrane

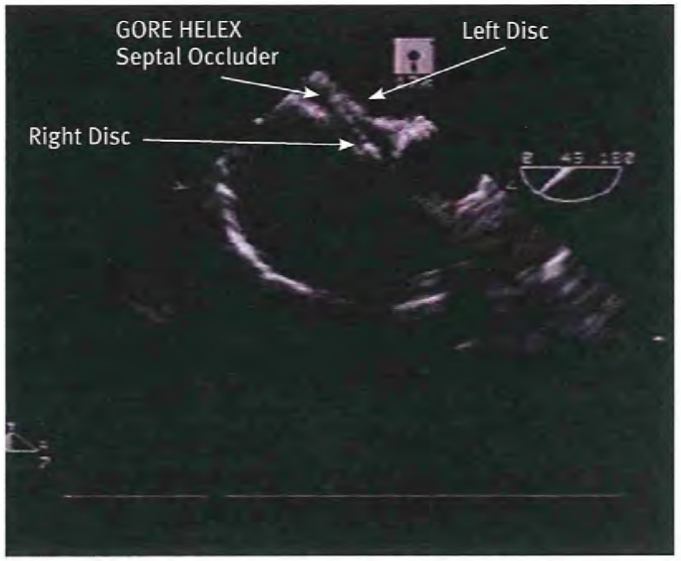


Figure C-4 –Hydrophilic-treated GORE HELEX Septal Occluder implant from ultrasound

Consult Instructions for Use

GORE HELEX SEPTAL OCCLUDER

Delivery System

Y-ARM

The "Y-Arm" of the GORE HELEX Septal Occluder simplifies deployment (Fig. C-5). The Gray Control Catheter and Tan Mandrel have only limited movement and must be locked in place at certain steps during device deployment.

At the distal end of the delivery system, the Tan Mandrel is co-axial within the Green Delivery Catheter and the Gray Control Catheter (Fig. C-6). Additionally, a stiffening wire runs co-axial within the Tan Mandrel. Midway along the delivery system, the Tan Mandrel bifurcates out at the Gray Control Catheter lumen, to provide separate control "handles" for the operator.

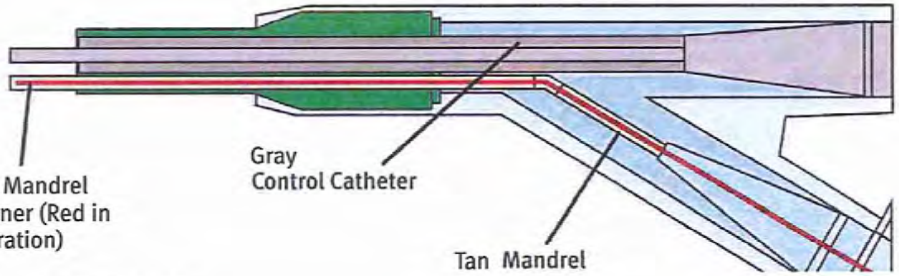


Figure C-5 – "Y-Arm"

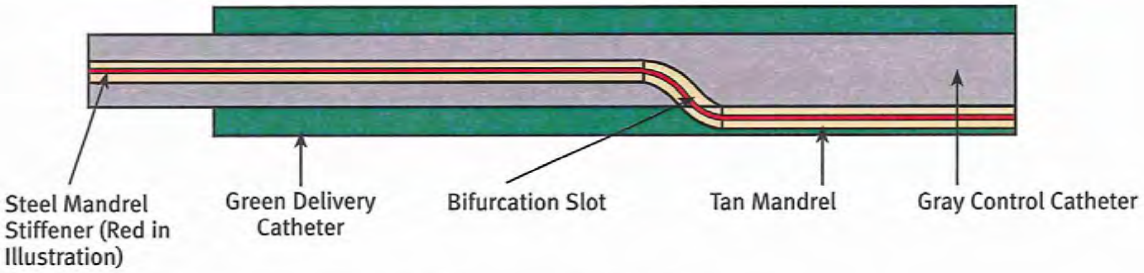


Figure C-6 – Longitudinal section of component bifurcation

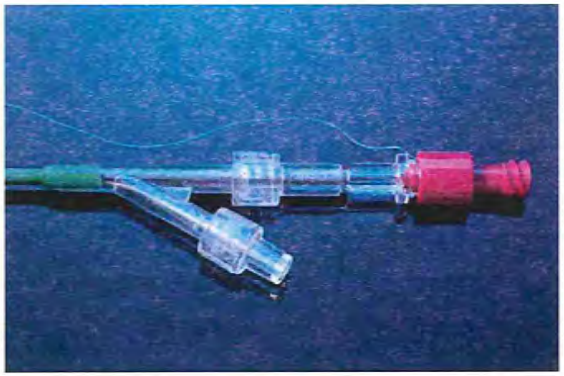


Figure C-7

Consult Instructions for Use

GORE HELEX SEPTAL OCCLUDER

Delivery System

Complete delivery system is used for deployment, repositioning and retrieval.

GREEN DELIVERY CATHETER

- Contains elongated Occluder
- 10 Fr diameter
- Perforated to allow delivery over 0.035" wire (Fig. C-8)
- Pre-shaped catheter positions the Occluder across the defect (Fig. C-9)
- Working length – 75 cm

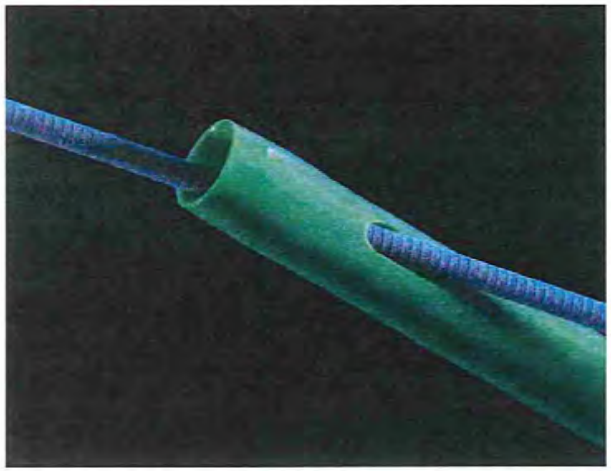


Figure C-8 – Guidewire slot with 0.035" guidewire in place

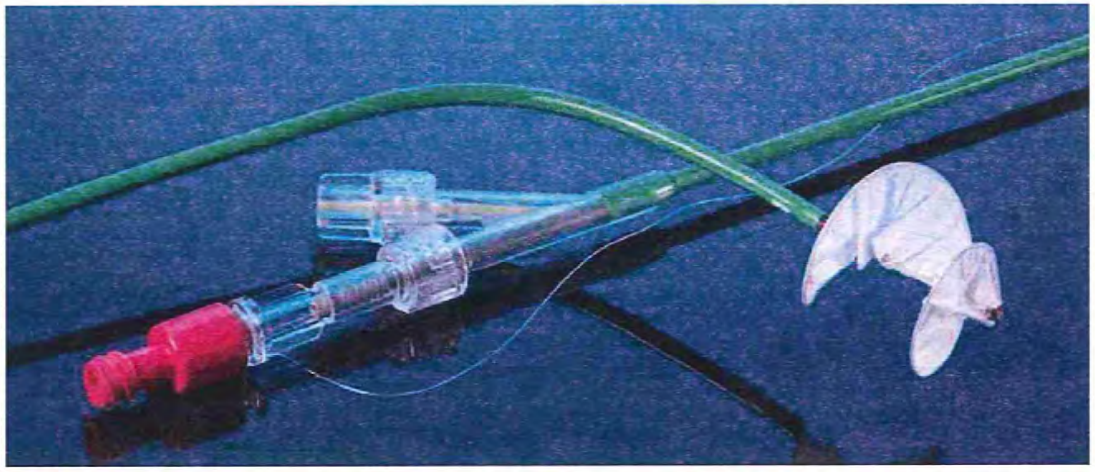


Figure C-9 – GORE HELEX Septal Occluder

Consult Instructions for Use

GORE HELEX SEPTAL OCCLUDER

Delivery System

GRAY CONTROL CATHETER

- Includes Retrieval Cord and Red Retrieval Cord Cap (Fig. C-10).
  - — Retrieval Cord holds Occluder to delivery system after lock release (Fig. C-11).
  - — Can be used to unlock and retrieve Occluder after lock release if necessary (Fig. C-11).

- "D" shaped Gray Control Catheter and Tan Mandrel lumen prevents rotation of components (Fig. C-12).
  - — Separate Tan Mandrel and Retrieval Cord lumens to prevent entanglement.
  - — Slotted tip allows lock loop to consistently deploy through the side of the catheter, reducing disc separation during lock release.

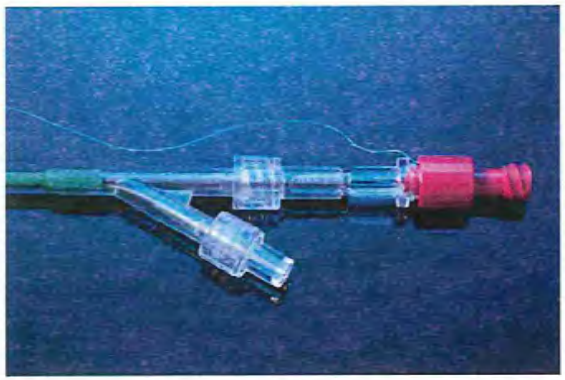


Figure C-10 – Red Retrieval Cord Cap secures end of Retrieval Cord to Gray Control Catheter

Figure C-11 – Retrieval Cord looped through the proximal eyelet

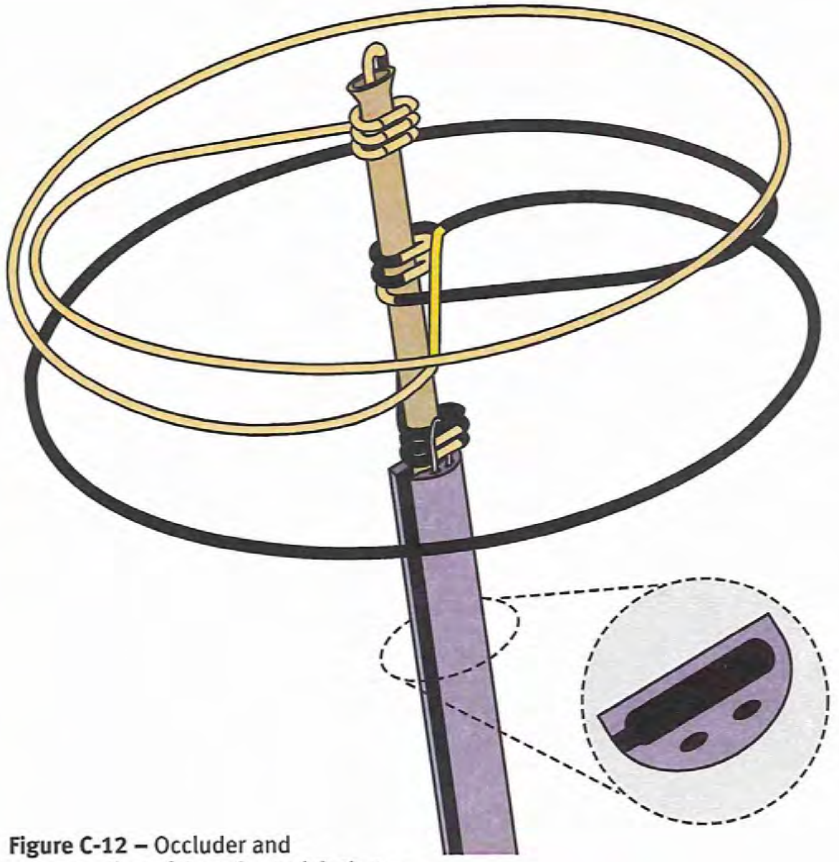


Figure C-12 – Occluder and cross-section of Gray Control Catheter

Consult Instructions for Use

GORE HELEX SEPTAL OCCLUDER

Delivery System

TAN MANDREL

- Controls configuration of the Occluder
- Retains the integral locking mechanism until release
- Pulling gently on the Tan Mandrel configures the Occluder into a circular shape

During assembly, the three eyelets and the ePTFE membrane perforations are threaded onto the Tan Mandrel. The locking loop is straightened and placed within the lumen of the Tan Mandrel. The Tan Mandrel tip is flared to retain the eyelets until lock release (Fig. C-13).

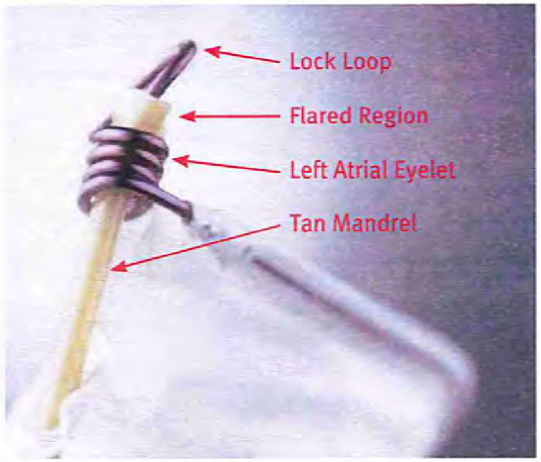


Figure C-13 – Tan Mandrel with flared tip

Consult Instructions for Use

GORE HELEX SEPTAL OCCLUDER

Delivery System

In Figure C-14, the Occluder is shown as it would appear prior to lock release and prior to loading the Occluder into the delivery system. The Retrieval Cord holds the right atrial eyelet of the Occluder to the tip of the Gray Control Catheter. The locking loop is held straight within the Tan Mandrel. The Mandrel Stiffener runs along a portion of the length of the lock loop within the Tan Mandrel.

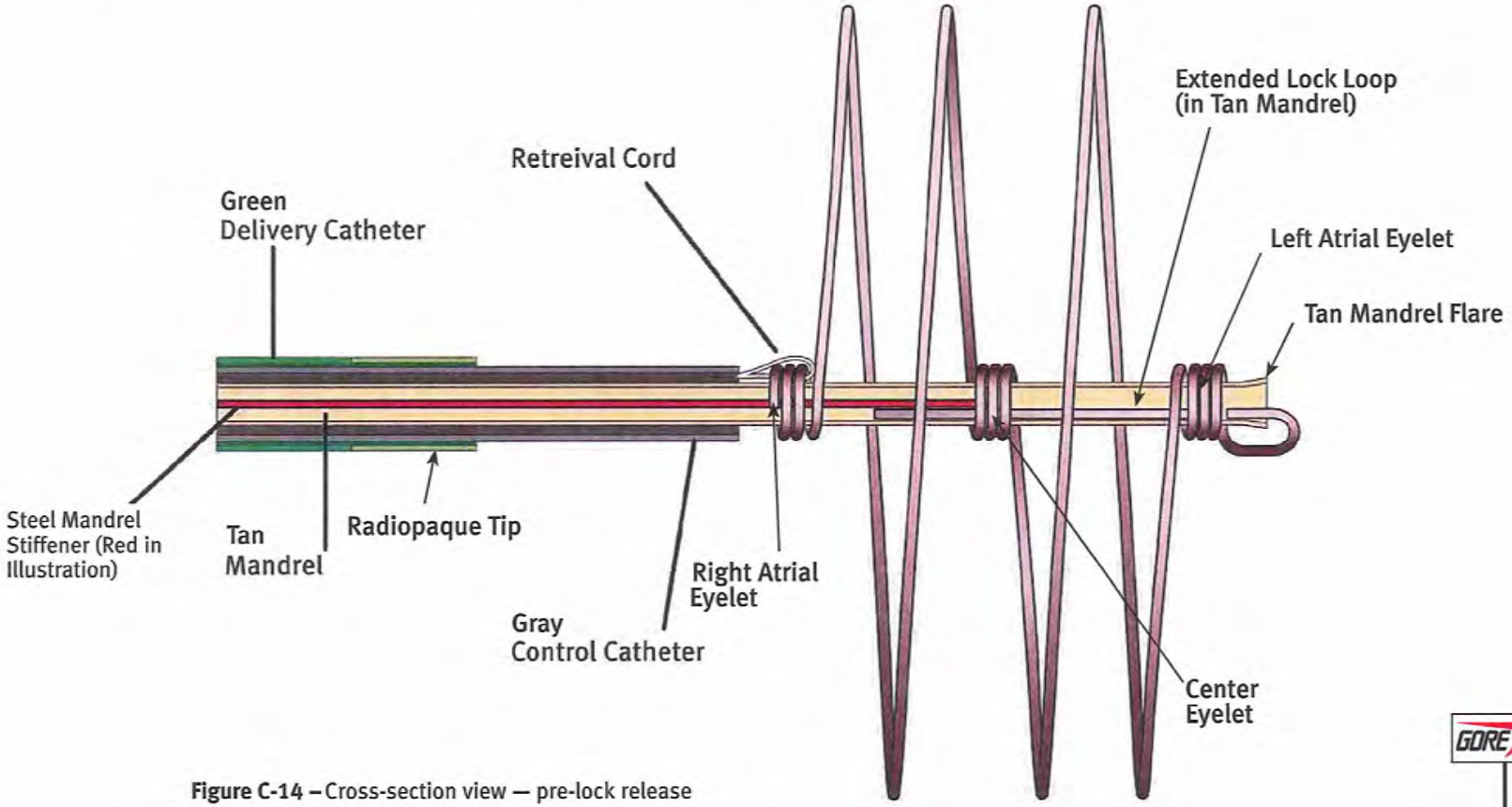


Figure C-14 – Cross-section view — pre-lock release

Consult Instructions for Use

GORE HELEX SEPTAL OCCLUDER

Delivery System

A firm and quick pull on the Mandrel Luer pulls the Tan Mandrel tip through the three eyelets and allows the locking loop to deploy through the slot in the Gray Control Catheter (Figs C-14 and C-15).

In Figure C-15, the Occluder is shown following lock release. The three eyelets are held closely together. The Tan Mandrel has been withdrawn into the Gray Control Catheter, allowing the lock loop to form through the slot at the tip of the Gray Control Catheter.

Once locked, the Occluder is still attached to the tip of the Gray Control Catheter by the Retrieval Cord.

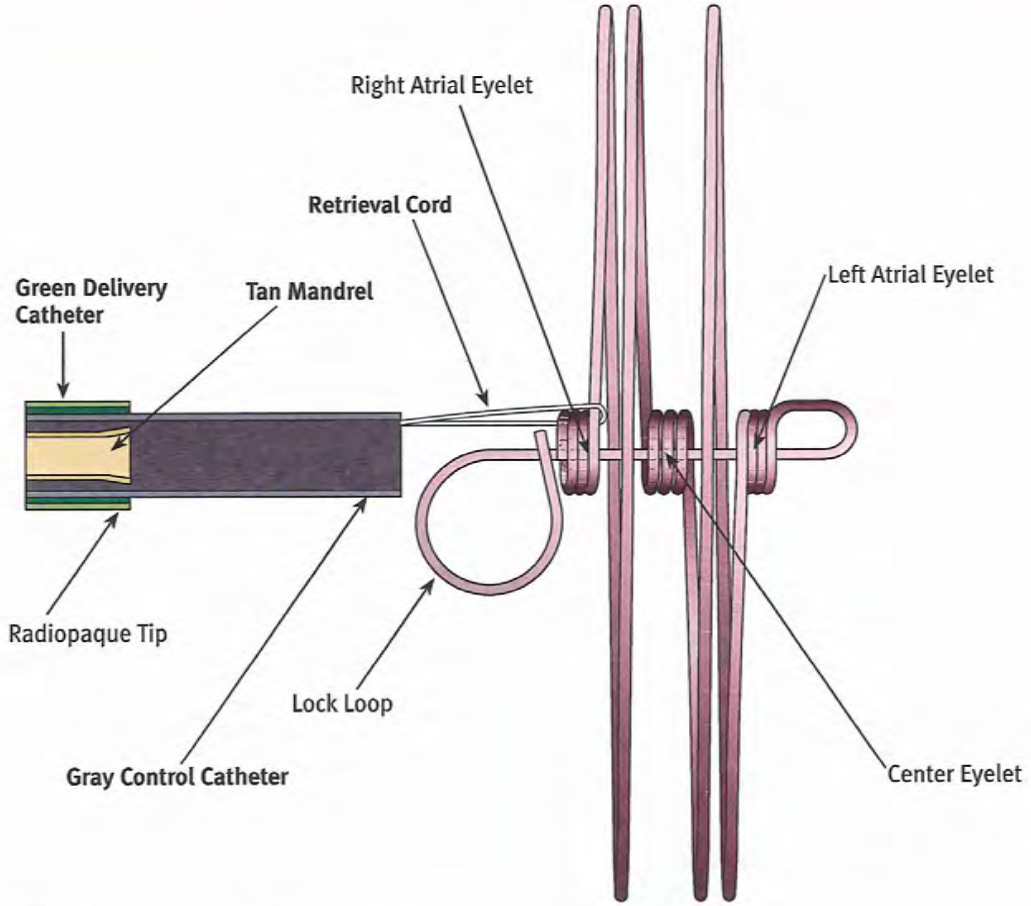


Figure C-15 – Cross-section view — locked

Consult Instructions for Use

GORE HELEX SEPTAL OCCLUDER

Indications / Contraindications

INDICATIONS / INTENDED USE

The GORE HELEX Septal Occluder is a permanently implanted prosthesis indicated for the percutaneous, transcatheter closure of atrial septal defects (ASDs), such as ostium secundum and patent foramen ovale.

CONTRAINDICATIONS

The GORE HELEX Septal Occluder is contraindicated for use in patients:

- With extensive congenital cardiac anomalies that can only be adequately repaired by cardiac surgery
- Unable to take anti-platelet or anticoagulant medications such as aspirin, heparin, or warfarin
- With anatomy where the GORE HELEX Septal Occluder size or position would interfere with other intracardiac or intravascular structures, such as cardiac valves or pulmonary veins
- With active endocarditis, or other infections producing bacteremia, or patients with known sepsis within one month of planned implantation, or any other infection that cannot be treated successfully prior to device placement
- Whose vasculature is inadequate to accommodate one of the GORE HELEX Septal Occluder Recommended Introducer Sheaths (Table 1)
- With known intracardiac thrombi

Consult Instructions for Use

GORE HELEX SEPTAL OCCLUDER

Warnings

WARNINGS

- The GORE HELEX Septal Occluder is not recommended for defects larger than 18 mm.
- The GORE HELEX Septal Occluder is not recommended for patients with a septal thickness of greater than 8 mm in the area of the occluder placement.
- The GORE HELEX Septal Occluder has not been studied in patients known to have multiple defects requiring placement of more than one device.
- The GORE HELEX Septal Occluder is not recommended for, and has not been studied in, patients with other anatomical types of ASDs that are eccentrically located on the septum (examples include sinus venosus ASD and ostium primum ASD), or fenestrated Fontan.
- The GORE HELEX Septal Occluder has not been studied in patients with significant atrial septal aneurysm.
- Regarding device deployment:
  - The defect and atrial chamber size should be evaluated by Transesophageal / Transoesophageal Echocardiography (TEE / TOE) or Intracardiac Echo (ICE) with color flow Doppler measurement to confirm that there is adequate space to accommodate the selected occluder size without impinging on adjacent cardiac structures (e.g., A-V valves, ostia of the pulmonary veins, coronary sinus, or other critical features).
  - There must be adequate room in the atrial chambers to allow the right and left atrial discs to lie flat against the septum with disc spacing equal to the septal thickness, and without interference with critical cardiac structures or the free wall of the atria.
  - The defect should be evaluated to ensure there is an adequate rim to retain the device in ≥ 75% of the circumference of the defect.
  - The selected occluder diameter should be at least two times the diameter of the defect (i.e., a 2:1 ratio of device diameter-to-defect diameter). Deploying the occluder in cases where the occluder diameter-to-defect diameter ratio is below 2:1 increases the risk of unsuccessful device placement and device embolization.
  - An occluder that pulls through the defect during disc confirmation may be too small and should be removed and replaced with a larger size.
- Embolized devices must be removed. An embolized device should not be withdrawn through intracardiac structures unless the occluder has been adequately collapsed within a sheath.
- If successful deployment cannot be achieved after two attempts, an alternative treatment for ASD closure should be considered. Consideration should be given to the patient's total exposure to radiation if prolonged or multiple attempts are required for the placement of the GORE HELEX Septal Occluder.
- The GORE HELEX Septal Occluder should be used only by physicians trained in its use, and in transcatheter defect closure techniques. The procedure should be performed only at facilities where surgical expertise is available.
- Patients allergic to nickel may suffer an allergic reaction to this device.

GORE HELEX SEPTAL OCCLUDER

Consult Instructions for Use

Precautions

PRECAUTIONS

Handling

- The GORE HELEX Septal Occluder is intended for single use only. An unlocked and removed occluder cannot be reused.
- The GORE HELEX Device is designed for single use only; do not reuse device. Gore does not have data regarding reuse of this device. Reuse may cause device failure or procedural complications including device damage, compromised device biocompatibility, and device contamination. Reuse may result in infection, serious injury, or patient death.
- Inspect the package before opening. If seal is broken, contents may not be sterile.
- Inspect the product prior to use in the patient. Do not use if the product has been damaged.
- Do not use after the labeled "use by" (expiration) date.
- Do not resterilize.

Procedural

- Patients should be heparinized sufficiently to maintain an Activated Clotting Time (ACT) greater than 200 seconds throughout the procedure.
- The GORE HELEX Septal Occluder should be used only in conjunction with appropriate imaging techniques to assess the septal anatomy and to visualize the wire frame. These techniques include multiplanar TEE / TOE or ICE, both with color flow Doppler, and fluoroscopy with real-time image magnification.
- Retrieval equipment such as large diameter sheaths, loop snares, and retrieval baskets should be available for emergency or elective removal of the occluder.
- Removal of an occluder should be considered if:
  - The lock fails to capture all three eyelets
  - The occluder will not come to rest in a planar position apposing the septal tissue
  - The selected occluder is too small and allows excessive shunting
  - There is impingement on adjacent cardiac structures

Consult Instructions for Use

GORE HELEX SEPTAL OCCLUDER

Precautions

PRECAUTIONS (continued)

Post-Implant

- Patients should take appropriate prophylactic antibiotic therapy consistent with the physician's routine procedures following device implantation.
- Patients should be treated with antiplatelet therapy, such as aspirin or clopridogrel bisulfate, for six months post-implant. The decision to continue antiplatelet therapy beyond six months is at the discretion of the physician.
- In patients sensitive to antiplatelet therapy, alternative therapies, such as anticoagulants, should be considered.
- Patients should be advised to avoid strenuous physical activity for a period of at least two weeks after occluder placement.
- Patients should have Transthoracic Echocardiographic (TTE) exams prior to discharge, and at 1, 6, and 12 months after occluder placement to assess defect closure.
- Fluoroscopic examination without contrast is recommended at 12 months post-procedure for patients with a 35 mm device with attention directed toward possible wire frame fractures.

Equipment Considerations

Facilities implanting the GORE HELEX Septal Occluder should have an interventional cardiac catheterization laboratory equipped with:

- High resolution fluoroscopic imaging equipment.
- Transesophageal Echocardiography (TEE) or Intracardiac Echocardiography equipment with color flow Doppler capabilities.
- A standard range of catheterization supplies including introducer sheaths (as noted below), guidewires, and sizing balloons.

Table C-1: Recommended Introducer Sheath Sizes

Without Guidewire	With Guidewire
10 Fr or greater (I.D. 0.131 in. / 3.33 mm)	13 Fr or greater (I.D. 0.171 in. / 4.33 mm)
9 Fr TERUMO PINNACLE® Introducer Sheath[1]	12 Fr COOK CHECK-FLO® Introducer Sheath
	11 Fr TERUMO PINNACLE® Introducer Sheath

[1] Although the sheath is designed to accommodate catheters up to 9 Fr in diameter, internal testing has shown compatibility of the introducer sheath with the GORE HELEX Septal Occluder catheter delivery system.

- Should the emergency retrieval of an embolized device become necessary, larger, Mullins-type sheaths, snare catheters (35 mm will capture all sizes) or retrieval baskets should be available.

The procedure should be performed only at facilities where surgical expertise is available.

This product is intended for use by physicians trained in the use of the GORE HELEX Septal Occluder and in transcatheter defect closure.

Consult Instructions for Use

GORE HELEX SEPTAL OCCLUDER

Choosing the Optimal Size

Evaluate the defect and the atrial dimensions using TEE and fluoroscopy:

- **Determine defect size using a low pressure sizing balloon inflated across the defect.**
- **There should be sufficient rim to hold the device in place and adequate room in the atria to allow the device to lie apposed to the septal tissue.**
- Recommended device-to-defect ratio is 2:1. Deploying the Occluder in patients where the device-to-defect ratio is less increases the risk for embolization and residual leaks.

The GORE HELEX Septal Occluder is available in diameters of 15, 20, 25, 30, and 35 mm, allowing closure of defects up to 18 mm.

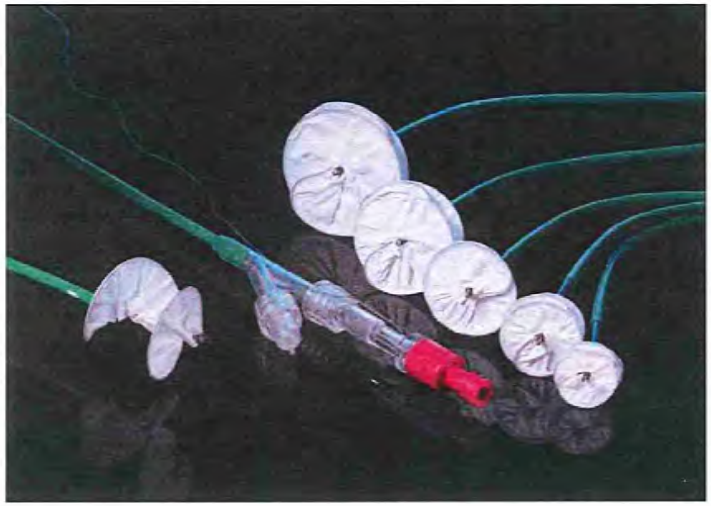


Figure C-16

Table C-2

Labeled Occluder Diameter (mm)	Nominal Defect Size (mm)
15	7.5
20	10
25	12.5
30	15
35	17.5

Consult Instructions for Use

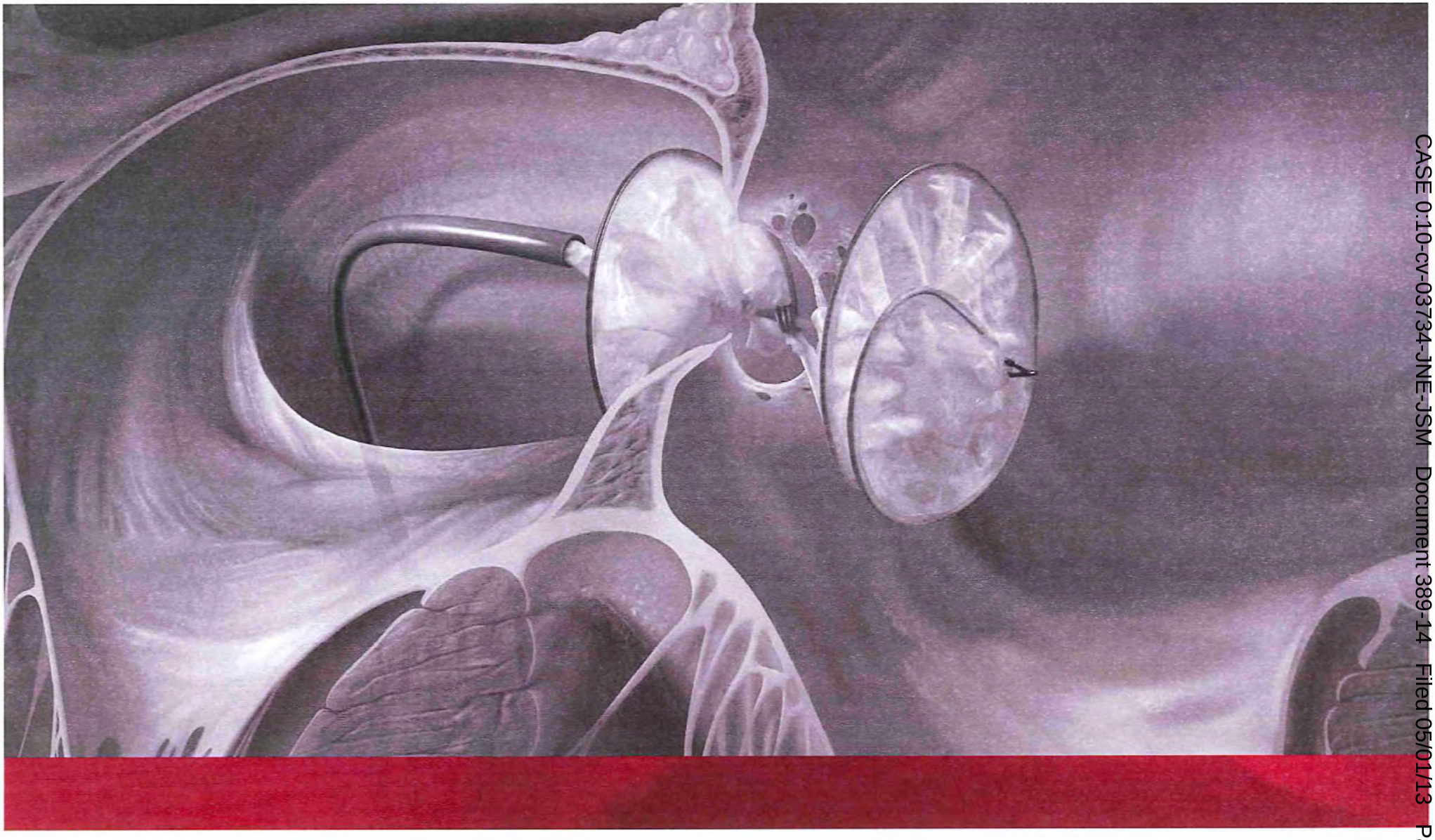
GORE HELEX SEPTAL OCCLUDER

Patient Considerations

- The patient whose vasculature is inadequate to accommodate one of the GORE HELEX Septal Occluder Recommended Introducer Sheaths (Page C-15).
- Activated Clotting Time (ACT) should be maintained at 200 seconds or greater throughout the procedure.
- Standard and accepted post-procedural antiplatelet and antibiotic therapy should be employed.
- Refer to the GORE HELEX Septal Occluder *Instructions for Use* (IFU) for patient warnings and precautions.

Consult Instructions for Use

GORE HELEX SEPTAL OCCLUDER



DEPLOYMENT INSTRUCTIONS

GORE HELEX SEPTAL OCCLUDER

AGA_GORE0442712
D-1

Deployment Instructions

The following pages describe the deployment of the GORE HELEX Septal Occluder.
Three major points are addressed:

Loading / Flushing

Disc Formation

Lock Release

The cardiologist is encouraged to practice deployments in a model, both on the tabletop and under fluoroscopy in order to become completely familiar with the appearance and behavior of the device.

Consult Instructions for Use

GORE HELEX SEPTAL OCCLUDER

Loading / Flushing

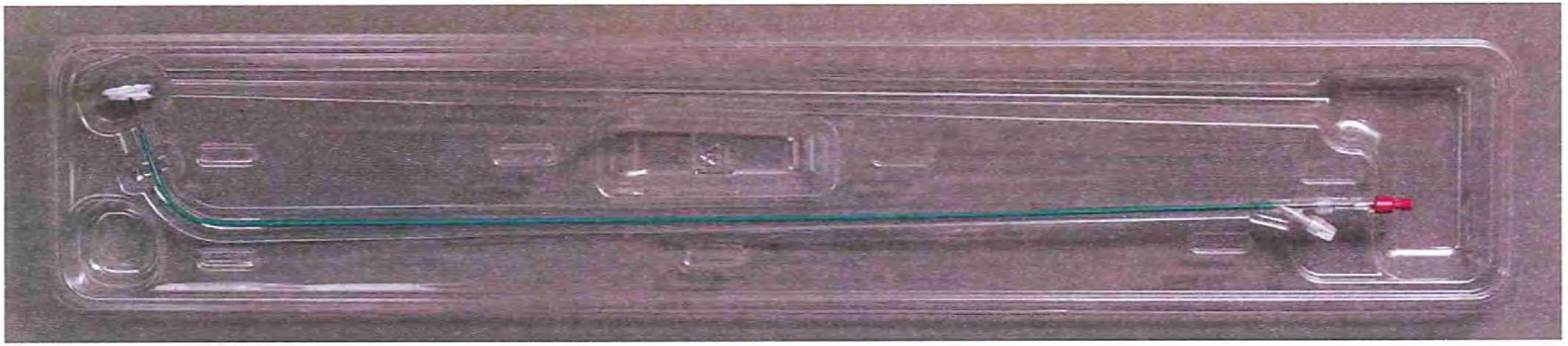


Figure D-1 – The GORE HELEX Septal Occluder Delivery System and Tray

The GORE HELEX Septal Occluder is provided in a sterile package ready to load. Prior to loading, the disc is fully formed and both the Gray Control Catheter Luer and the Mandrel Luer are locked. The Retrieval Cord is held tightly by the Red Retrieval Cord Cap (Fig. D-1).

To begin the loading process, submerge the GORE HELEX Septal Occluder in heparinized saline. Keep the delivery system straight during loading.

Fill a syringe (12 – 30 cc) with heparinized saline, attach it to the Red Retrieval Cord Cap and flush to fill the system.

Consult Instructions for Use

GORE HELEX SEPTAL OCCLUDER

Loading / Flushing

To begin loading, assure the Mandrel Luer is locked. Grasp the "Y-Arm" and loosen the Gray Control Catheter Luer (Fig. D-2). With the right hand, gently pull (retract) the Gray Control Catheter (Fig. D-3). The Mandrel Luer is locked, holding the Tan Mandrel in place. The Occluder will be easily drawn into the Green Delivery Catheter.

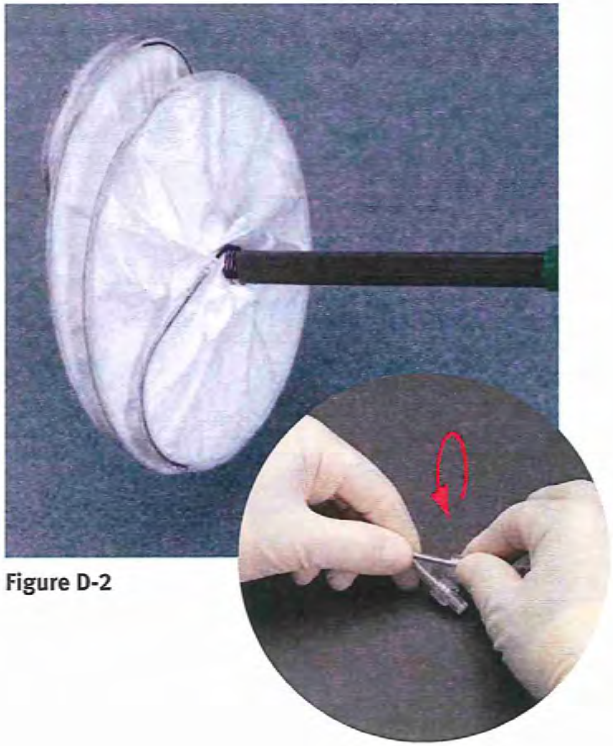


Figure D-2

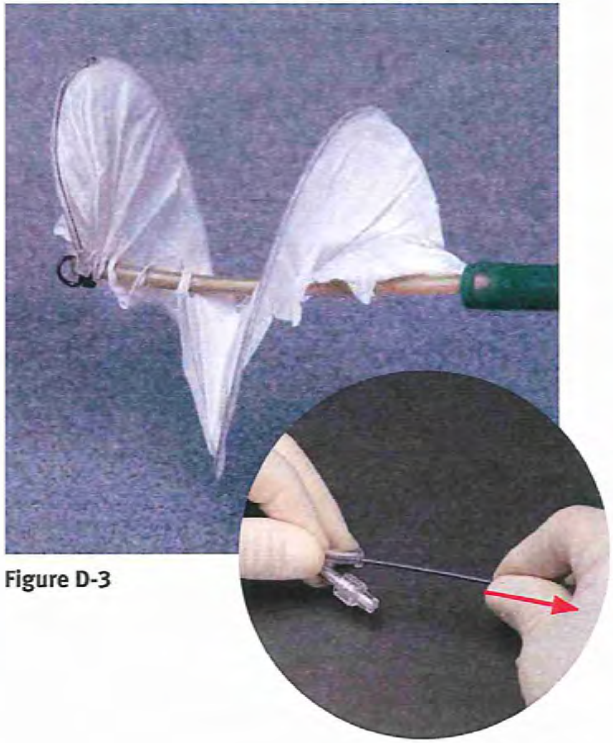


Figure D-3

Consult Instructions for Use

GORE HELEX SEPTAL OCCLUDER

Loading / Flushing

- Once the Tan Mandrel tip and Occluder begin to bow, (Fig. D-4), loosen the Mandrel Luer.
- Grasp the Gray Control Catheter and continue to pull until the entire Occluder is inside the Green Delivery Catheter (Fig. D-5).
- Once the entire Occluder is loaded into the Green Delivery Catheter, reload the syringe with heparinized saline, and flush vigorously.
- Leave the syringe attached as the delivery system is moved to the table; flush again just prior to inserting the catheter into the sheath.

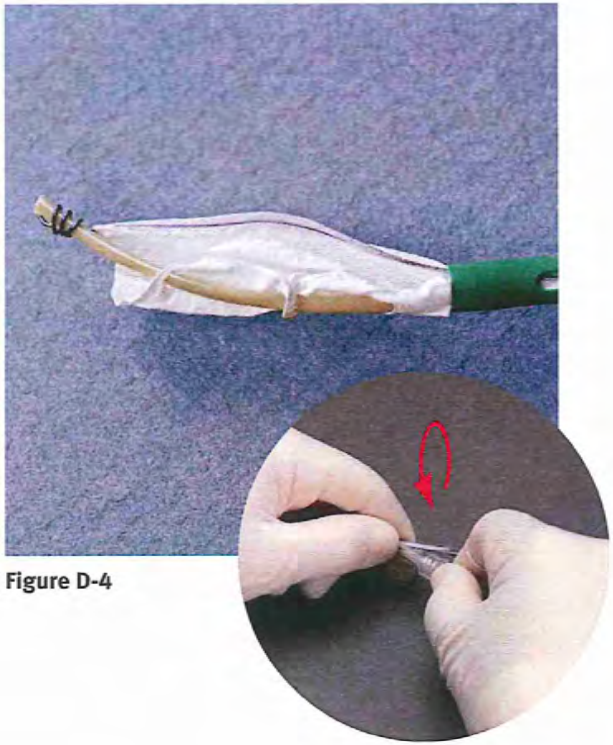


Figure D-4

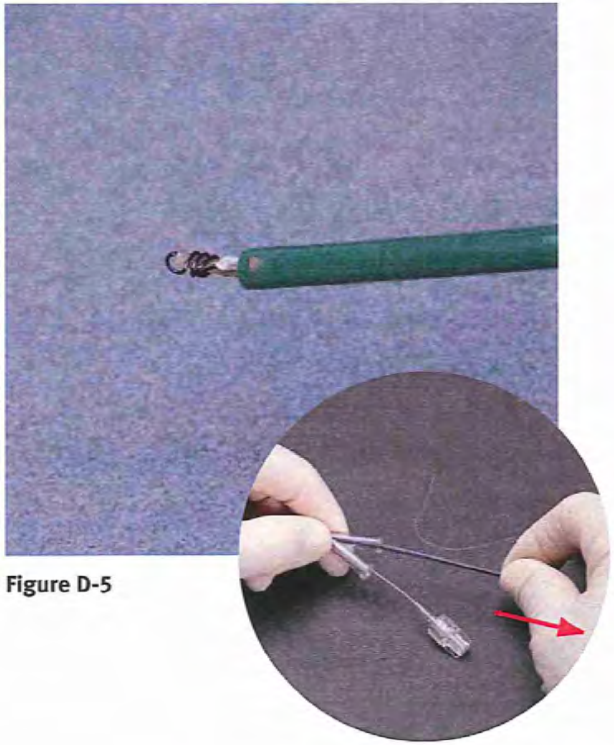


Figure D-5

Consult Instructions for Use

GORE HELEX SEPTAL OCCLUDER

Advancing the System to the Defect

The GORE HELEX Septal Occluder has been designed as a self-contained delivery system and may be advanced across many defects directly.

Physicians may choose to access the defect with a guidewire or a long sheath in order to select a particular fenestration or save time accessing a small tunnel.

The GORE HELEX Septal Occluder delivery system can be advanced over a wire using the Guidewire Slot at the distal end of the Green Delivery Catheter. In that case, a larger introducer sheath must be employed. These include an 11 Fr TERUMO PINNACLE® Introducer Sheath, a 12 Fr COOK CHECK-FLO® Introducer Sheath, or any introducer sheath that is labeled 13 Fr or greater.

If a long sheath is employed, it must be at least 10 Fr and less than 75 cm in length.

Consult Instructions for Use

GORE HELEX SEPTAL OCCLUDER

Deployment

When ready to deploy, confirm by echocardiography that the tip of the catheter is across the defect.
The delivery system will appear as in the photo below (Fig. D-6).

- Both Luers are unlocked.
- The Gray Control Catheter is retracted sufficiently to bring the entire Occluder within the Green Delivery Catheter.
- 3 to 4 cm of the Tan Mandrel is exposed between the Luer and hub.

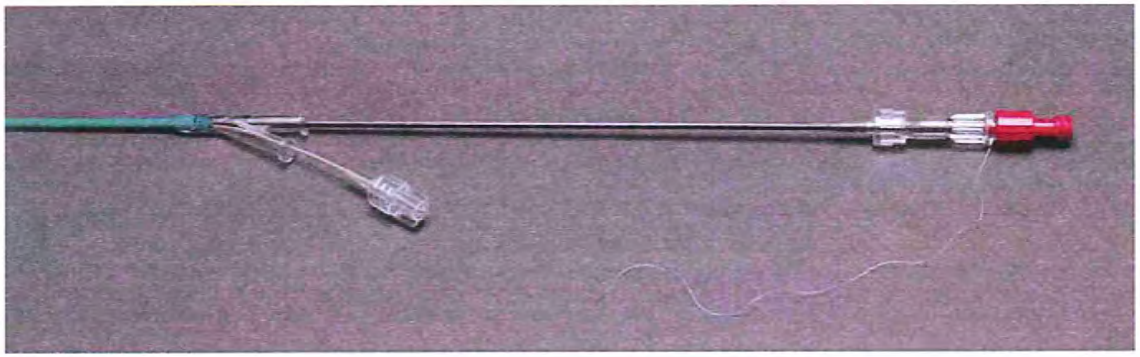


Figure D-6

Left Atrial Disc Deployment

To begin deployment of the left atrial disc, grasp the "Y-Arm" in the left hand. All delivery motions of the Occluder should be observed on fluoroscopy with the intra atrial position confirmed by echocardiography.

- Push the Gray Control Catheter to advance (Fig. D-7a, next page).
  – Notice that the Tan Mandrel moves as the Gray Control Catheter is pushed.
- Continue pushing lightly until the Mandrel Luer engages the "Y-Arm".
- Pinch (hold) the Gray Control Catheter with the left thumb and forefinger to hold Occluder in position (Fig. D-7b, next page).
- Pull the Mandrel Luer gently to form the disc (Fig. D-7c, next page).
  – The operator will feel a light tactile “stopping” sensation.
  – Avoid pulling left atrial eyelet against the Green Delivery Catheter tip.
- Repeat the “Push / Pinch / Pull” sequence until the left atrial disc is formed to complete the deployment.

Consult Instructions for Use

GORE HELEX SEPTAL OCCLUDER

Left Atrial Disc Deployment

PUSH

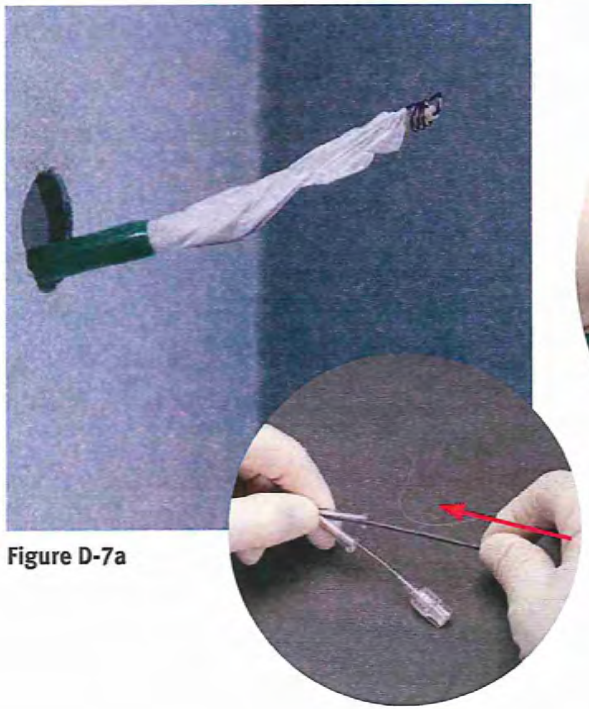


Figure D-7a

PINCH

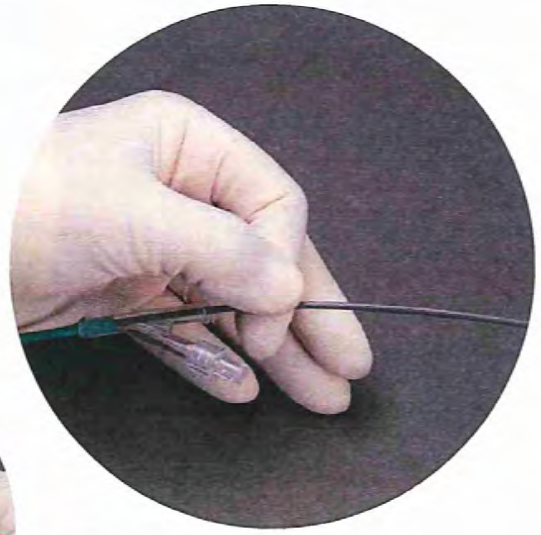


Figure D-7b

PULL

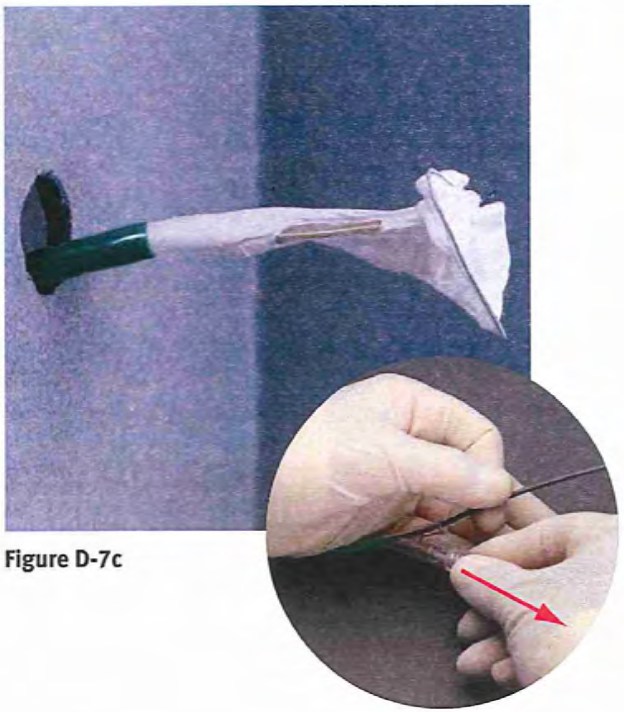


Figure D-7c

Consult Instructions for Use

GORE HELEX SEPTAL OCCLUDER

Transition — Left-to-Right

Once the central eyelet exits the catheter tip, the operator will prepare to appose the formed left atrial disc against the septum.

- Pull lightly on Tan Mandrel to flatten left atrial disc (Fig. D-8a).
- Pull entire delivery system gently to appose the left atrial disc to the septum (Fig. D-8b).
  – Confirm contact with the septum on echocardiography.
  – Do not pull firmly against the septum.
- Hold Gray Control Catheter and pull the Green Delivery Catheter gently until the "Y-Arm" contacts the Mandrel Luer to prepare for right atrial disc deployment.
- Tighten the Mandrel Luer (Fig. D-8c).

Figure D-8a – Left disc formation complete, formed left disc presented to septum

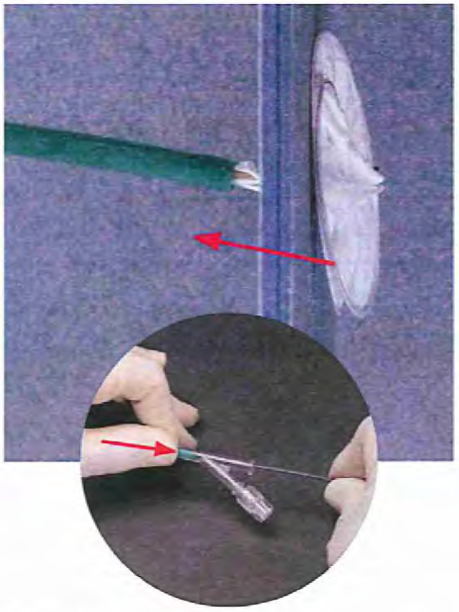


Figure D-8b – Left hand pulls, right hand holds

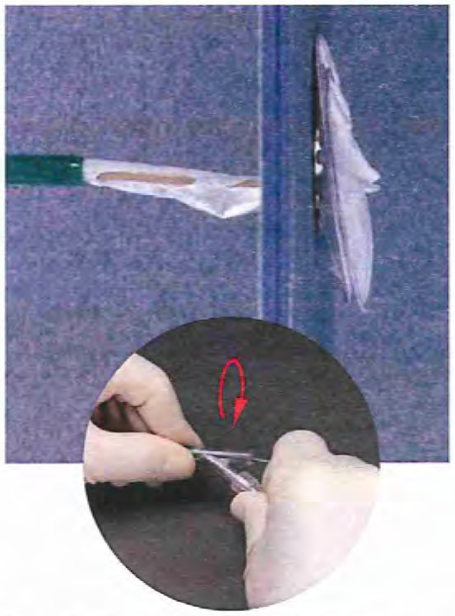


Figure D-8c – Tighten Tan Mandrel Luer

Consult Instructions for Use

GORE HELEX SEPTAL OCCLUDER

Right Atrial Disc Deployment

To deliver the right atrial disc:

- Hold the Green Delivery Catheter in the left hand to stabilize the device against the septum.
- Push the Gray Control Catheter smoothly with the right hand to form the right atrial disc (Fig. D-9).
- Tighten the Gray Control Catheter Luer (Fig. D-10).

The Occluder is now fully formed and prepared for lock release.

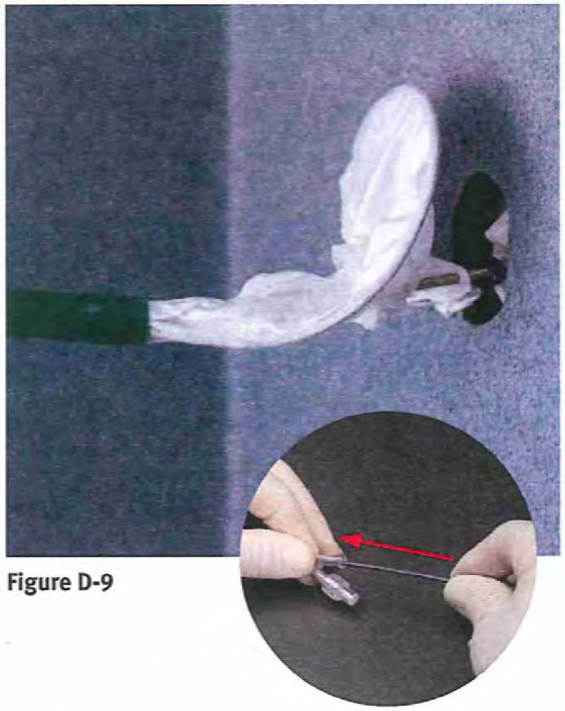


Figure D-9

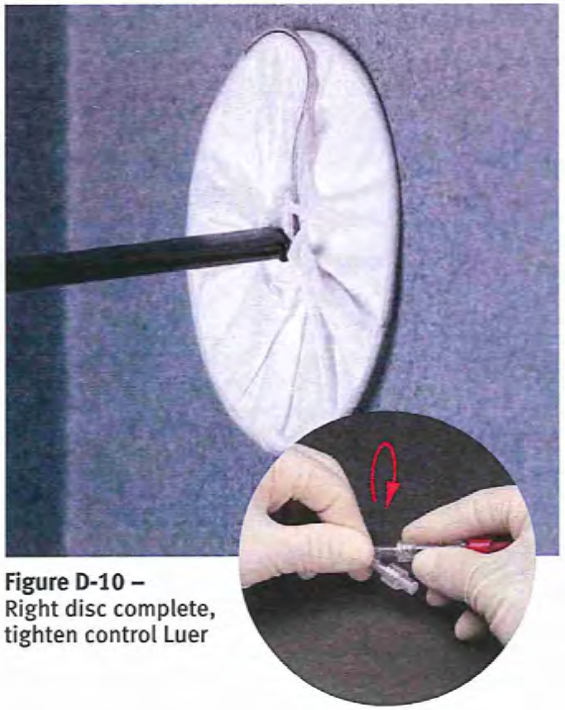


Figure D-10 –
Right disc complete, tighten control Luer

Consult Instructions for Use

GORE HELEX SEPTAL OCCLUDER

Lock Release

Lock release is a critical step in Occluder deployment and should be performed under ciné to ensure accuracy. Tension on the septum, caused by failure to fix the Gray Control Catheter position, may pull the Occluder through the defect from left-to-right. Allowing the Gray Control Catheter to push against the right disc may dislodge the Occluder to the left.

When appropriate, confirm position of the device on echocardiography.

- Remove the Red Retrieval Cord Cap and assure that the Retrieval Cord is free (Fig. D-11).
- Hold the "Y-Arm" with left hand to prepare for lock release.
- Loosen Mandrel Luer (Fig. D-12).
- Pull the Tan Mandrel firmly and quickly with right hand to release the lock (Fig. D-13).
  - Lock loop deploys through slotted tip while the Occluder is held in position between the tip of the Gray Control Catheter and the flare on the Tan Mandrel tip.
- Continue to the pull the entire length of the Tan Mandrel from the Green Delivery Catheter while holding the Green Delivery Catheter in a fixed position.

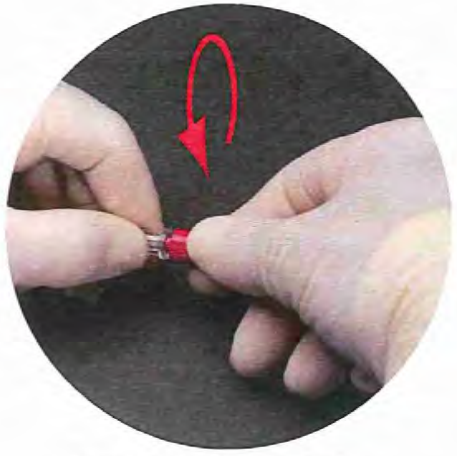


Figure D-11 – Remove Red Retrieval Cord Cap

Figure D-12 – Loosen Mandrel Luer

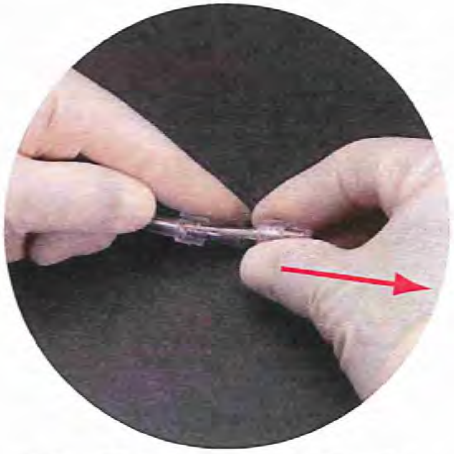


Figure D-13 – Quick, firm pull on the Tan Mandrel to lock

Consult Instructions for Use

GORE HELEX SEPTAL OCCLUDER

Post-Lock Considerations

The Occluder may change shape abruptly as the lock is released and as the Occluder conforms to the shape of the septum. **The Occluder is compliant and the left and right discs may not appear parallel; as an example in the closure of a defect with deficient anterior-superior rim, it may be seen to be "embracing" the aorta.**

Now that the Occluder is loosened from the delivery system, a final echocardiographic analysis can be performed. Remember, the Occluder is still tethered to the delivery system by the Retrieval Cord should removal be required.

Trivial residual leaks are likely to close quickly, often within the first few days following the procedure. Clinical experience has shown that small to moderate residual leaks typically close within six months of implantation. It is unlikely that residual leaks of greater than 3 mm will close. If atrial dimensions allow, a larger device will likely improve defect closure.

Consult Instructions for Use

GORE HELEX SEPTAL OCCLUDER